

EXHIBIT 4

Dental Conc

HOGAN & HARTSON

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November 22, 2006

Howard M. Holstein
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BY ELECTRONIC MAIL AND HAND DELIVERY

Mr. Timothy A. Ulatowski
Director, Office of Compliance (HFZ-300)
Center for Devices and Radiological Health
Food and Drug Administration
2094 Gaither Road
Rockville, MD 20877

Re: SleepRight® Rx Advance Mouth Guard

Dear Mr. Ulatowski:

On October 20, 2006, we informed the Food and Drug Administration ("FDA") that Splintek® is currently promoting its line of SleepRight® Adjustable Night Guard devices for over-the-counter ("OTC") use to "protect teeth from clenching & grinding." Our review of the Food and Drug Administration's ("FDA") premarket notification ("510(k)") database shows that Splintek apparently has not obtained FDA premarket clearance or approval to commercially distribute this device for OTC use.

It now has come to our attention that Splintek® also is promoting the SleepRight® Rx Advance mouth guard ("SleepRight Rx") for indications for use that FDA has not cleared, including protection against TMJ. Attached is a copy of an advertisement for the SleepRight® Rx Advance mouth guard that appeared in the November 2006 issue of Dental Drug Products.

I. BACKGROUND

Dental mouth guards are unclassified devices. Persons intending to market a dental mouthguard must submit and obtain FDA clearance of a 510(k) notification before marketing the device.

FDA's 510(k) database indicates that the agency cleared Splintek's EZ Splint and EZ Splint PM oral occlusal appliance or splint devices on October 17, 2003 (K022809). The FDA cleared the device for prescription use to protect against teeth grinding, bruxism, and jaw clenching; for short-term pain relief from muscle spasm due to occlusal interference; and for the prevention of chronic

Mr. Timothy A. Ulatowski
November 22, 2006
Page 2

tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth.

Splintek's web site lists the company's address as 3325 Wyoming St., Kansas City, MO 64111. The web site also show the following telephone contact information: Toll-Free (800) 792-0865; Local (816) 531-1900; and Fax (816) 531-1968.

II. ANALYSIS

In addition to promoting the SleepRight Rx for fast relief for TMJ & Muscle Pain, the enclosed advertisement states, among other things, that the device:

- "Protects, TMJ, and dental work from clenching & grinding;"
- "May save tooth enamel from chipping, cracks, & fractures;" and
- "Protecting the TMJ can help reduce head, neck & back tension."

FDA cleared the SleepRight Rx (K022809; October 17, 2003) for prescription use for:

- Protection against teeth grinding, bruxism, and jaw clenching;
- Short-term pain relief from muscle spasms due to occlusal interference;
- For the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the posterior mandibular and maxillary teeth."

The attached advertisement goes beyond the FDA-cleared indications for use. Although FDA cleared the SleepRight Rx for "Short term pain relief from muscle spasms due to occlusal interference," the agency did not clear the device for specific use in reducing head, neck & back pain. Similarly, although FDA cleared the SleepRight Rx for the prevention of chronic tension and the TMJ syndrome, the agency did not clear the device for use in treating all incidents of the TMJ syndrome irrespective of the cause of that syndrome. The agency only cleared the device for the prevention of the TMJ syndrome that is caused by chronic jaw clenching.

III. CONCLUSION

In sum, Splintek is promoting the SleepRight Rx Advance Mouth Guard for indications for use that go beyond those that FDA-cleared 510(k) for the device (K022809). Therefore, when promoted for these non-FDA cleared or approved claims, the SleepRight Rx devices are adulterated and misbranded. We request that the Office of Compliance take appropriate enforcement actions to prevent Splintek from continuing to distribute the adulterated and misbranded line of SleepRight Rx devices for relief for TMJ and muscle pain, irrespective of the cause of that pain.

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* * * * *

Please call me if you have any questions regarding this letter or if we can be of further assistance in FDA's investigation of this matter.

Sincerely,

A handwritten signature in cursive script, appearing to read "Howard Holstein".

Howard M. Holstein

Attachment

cc: Robert L. Spencer, Esq.



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Dr. Busch, TLC

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getting their teeth cleaned, but also players are telling them, 'Hey, you know this is important: We wear mouthguards in the game; it's important for you guys to wear mouthguards when you're playing sports, or when you go to bed to keep from grinding.' The players are helping teach the kids.

"When we're in the spotlight in the NFL, we've got to use it in a positive way helping out kids. If they'll listen to you, you've got to be a positive influence. With my mom being a dental assistant, I grew up knowing dental care is important."

Dr. Busch said Colquitt and his teammates were a perfect complement to a great event. "The kids think that if the football players support what we're doing here, then it must be cool," he said. "Having Dustin as our spokesperson for the Team Smile program is great. He's awesome with the kids, and he motivates them to take care of their mouths."

MetLife sponsored a Team Smile dinner Saturday night at Kauffman Stadium, while Colgate handed out about 10,000 toothbrushes prior to the football game. The Colgate Bright Smiles, Bright Future dental van made its first visit to an NFL game, and 75 children were screened on Saturday.

The children were not the only ones smiling. UMKC dental student Patrick Lancaster said providing care to the needy children provides a great feeling to the caregivers as well. "This is very nice," he said, "especially when the little ones are really ap-

NEW SleepRight[®]
ADJUSTABLE

**Fast Relief for
TMJ & Muscle Pain**

- Works great on grinding & clenching
- May save tooth enamel from chipping, cracks, & fractures
- Protecting the TMJ can help reduce head, neck & back tension
- Designed by a specialist in dentistry
- Increase patient compliance
- Cost effective! Requires no impressions, no lab time, saves chair time

Also available in mint

Flexible wings shape at body temp. to increase stability.

Durable bitepads adjust to fit all sizes & protect teeth.

Band is anatomically designed to increase comfort.

Spt ntek designing teeth & saving smiles

Call for special discounts on our new Advance products! **1.888.792.0865**

Use 343 on card or at www.dentalproducts.net

tri hawk 

**A sharp eye for
best in burs!**

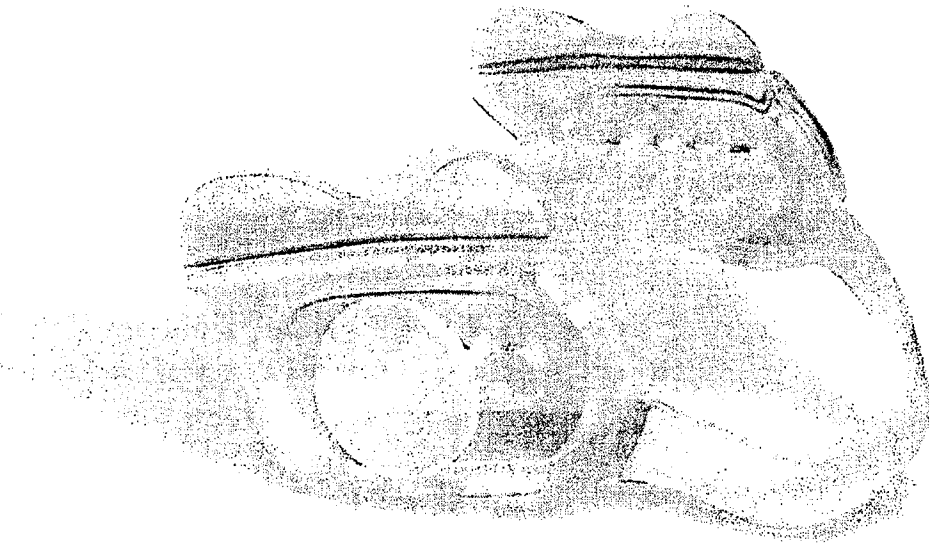
ADA 100%



Use 344 on card or at www.dentalproducts.net

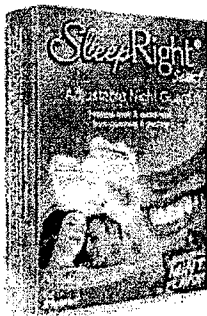
ATTACHMENT 1

Teeth grinding? You need to know what this is.



SleepRight®

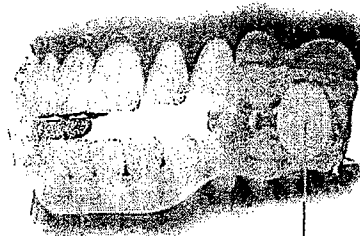
Adjustable Night Guard



- Fits comfortably to protect teeth from clenching & grinding
- No boiling, not bulky, fits all sizes
- Designed by a dental specialist
- Most durable guard available, backed by a 90-day warranty

\$69.95 (plus shipping & handling)
30-day money back guarantee

 **Splintek®** Designing Health & Comfort



Shapes at Body
Temperature

Adjustable Technology
4 Bitepad Positions

Contact us to order, receive FREE information, or find a retailer near you

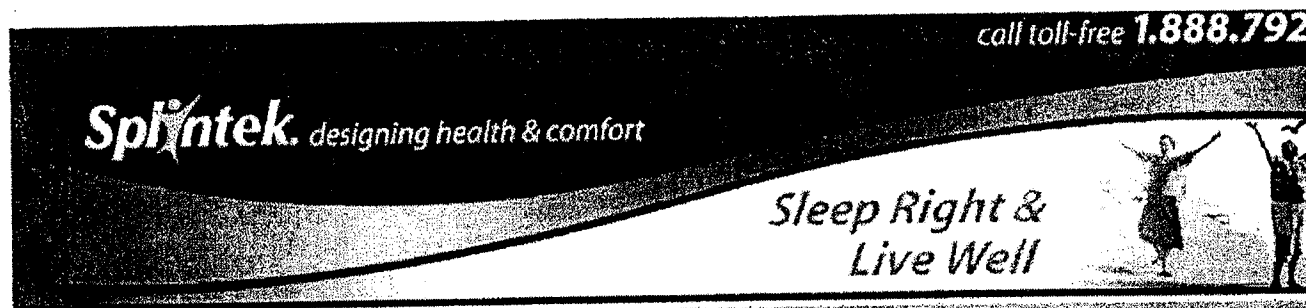
1.888.792.0865 • sleepright.com

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ATTACHMENT 2

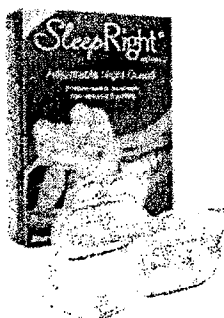
SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

Page 1 of 2



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New! SleepRight Adjustable Night Guard Advance



New & improved to be more durable, comfortable, and stable.
> more information

Select Flavor

[Buy Now](#)

Only available here!

\$99.95 (\$89.95 for 2 or more)

Available in a natural mint flavor

30-day - money back guarantee

90-day - replacement warranty

Includes one night guard, one carrying case, and fitting instructions.

SleepRight Adjustable Night Guard Select



Original design that fits most individuals and recommended for sleep.

> more information

Select Flavor

[Buy Now](#)

\$69.95 (\$59.95 for 2 or more)

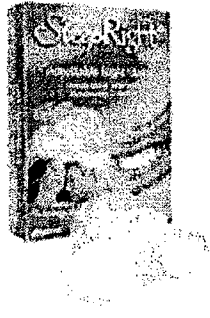
Available in natural mint flavor or cinnamon flavor

30-day - money back guarantee

90-day - replacement warranty

Includes one night guard, one carrying case, and fitting instructions.

SleepRight Adjustable Night Guard Select Low-Profile



Recommended for sensitive gums and/or a small mouth.
> more information

Select Flavor

[Buy Now](#)

\$69.95 (\$59.95 for 2 or more)

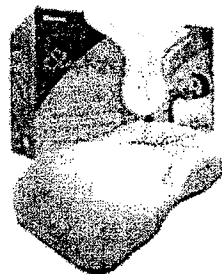
Available in natural mint flavor or cinnamon flavor

30-day - money back guarantee

90-day - replacement warranty

Includes one night guard, one carrying case, and fitting instructions.

SleepRight Side Sleeping Pillow



Uniquely designed memory foam pillow for side sleepers.
> more information

Select Size

[Buy Now](#)

**\$69.95 - 16" Length
\$99.95 - 24" Length**

5-Year Warranty

All sales final on pillow

Includes one memory foam pillow and one washable, hypo-allergenic, cotton velour cover.

ErgoPic



Ergonomically dental pics.
> more information

Please call to c
1.888.792.0861

\$6.95

Includes 50 re
dental pics and
carrying case.

SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

Page 2 of 2

SleepRight System! Purchase a 16" pillow for \$30, or a 24" pillow for \$50, or a 24" x 5" pillow for \$60 when you purchase it with SleepRight Adjustable Night Guard! Must place your order over the phone to receive this discount. 1.888.792.0865

Orders placed after 12pm CST will be shipped out the next business day.

Orders placed after 12pm CST on a Friday, Saturday, or Sunday will be shipped out the following Monday, despite the chosen shipping method.

The SleepRight Adjustable Night Guard is not recommended without a prescription for people with disorders of the temporomandibular joint (TMJ or TMD). TMJ problems can only be diagnosed by a dentist or health professional. SleepRight Adjustable Night Guard is available by prescription for different intended uses that can only be diagnosed by a health professional.

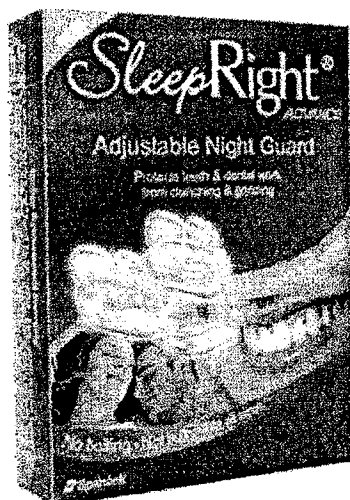
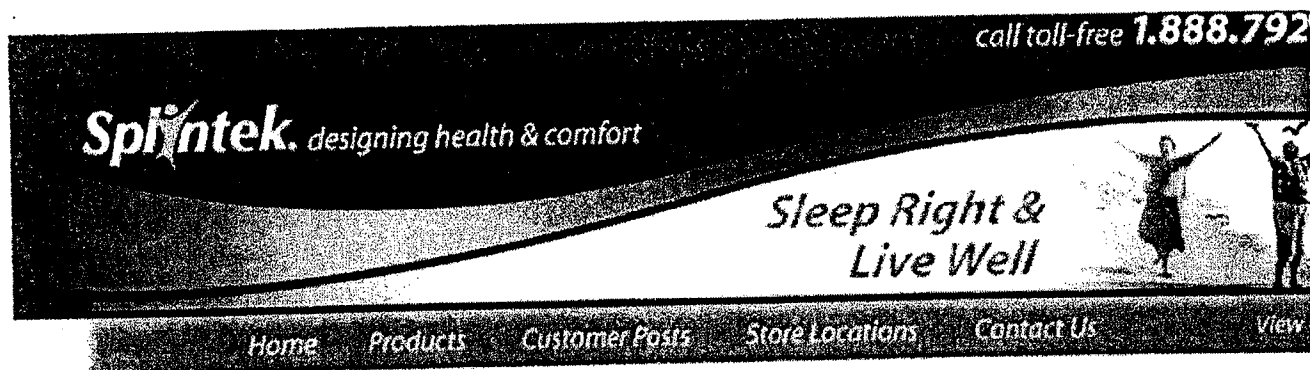
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SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

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SleepRight[®]
ADVANCE

SleepRight Select
SleepRight Select Low-Profile

Frequently Asked Questions
Philosophy
Care & Fitting Instructions
Satisfied Customers



 SleepRight Advance is our new & improved design that is more durable, stable, and comfortable!

Select Flavor

Only available here!

\$99.95 each (89.95 each for 2 or more)

Available in a natural mint flavor.

Includes one night guard, one carrying case, and fitting instructions.

30-Day Money Back Guarantee
If you are dissatisfied with the SleepRight Night Guard for any reason, simply return it to the place of purchase within 30-days from original purchase date for a refund.

90-Day Replacement Warranty
SleepRight is the most durable night guard on the market. If you clench or grind through the SleepRight Night Guard within 90-days from original purchase date,

Splintek has improved the design of the **bitepads**, the **frontal band**, and the **stability** make the SleepRight Advance more durable, comfortable, and stable than the SleepRight Select. The Advance bitepads are more durable because they are engineered using a dense, higher quality material. The wider frontal band is anatomically designed with a bridge to prevent the strap from sliding and feature more bendable hinges to reduce pressure points. The stability wing is more flexible allowing the wings to move with your mouth for increased comfort.

- Protects teeth and dental work from clenching and grinding
- Designed by a dentist
- Adjustable technology designed to fit all sizes
- No boiling required
- Easy to fit in seconds
- Comfortable and not bulky

The SleepRight Adjustable Night Guard was designed by a specialist in dentistry and has been used by thousands of doctors worldwide. The SleepRight's state-of-the-art technology designed specifically to protect teeth from bruxism, commonly referred to as clenching and grinding the teeth. Studies have reported that chronic jaw clenching and grinding has been associated with head, neck, shoulder, and back tension.

Can also be worn for performance enhancement during non-contact sporting activities where the natural tendency to clench and grind the teeth may occur, such as: golf, weightlifting, tennis, cycling, bowling, archery, skeet shooting, etc.

How does the SleepRight Night Guard work?

simply send the used night guard to Splintek, 3325 Wyoming St., Kansas City, MO 64111. You must include proof of purchase, your name, and return address. Please allow up to 2 weeks to receive your replacement.

Indications: SleepRight Adjustable Night Guard protects teeth and dental work from clenching and grinding.

Caution: For all TMJ concerns, please consult your health care provider who may prescribe a SleepRight Rx. Do not use for more than 12 hours in a 24 hour period. Recommended for day time or night time use, not both. Not for children under 12 years of age. If you experience jaw pain, clicking, jaw noises, tooth movement, or other symptoms, see your health care provider. Discontinue use and replace if breakage occurs.

Clenching and grinding teeth has been classified as a neuromuscular disorder. Overactive muscles can cause chipping, fractures, excessive wear and loosening of the teeth. So studies report that chronic jaw clenching and teeth grinding may be related to head and neck muscle tension and pain in the jaw joints. The SleepRight's articulating bitepads, made of resilient hybrid material, slip comfortably between your teeth and are designed to re-establish your natural freeway space. While the SleepRight protects teeth from clenching and grinding, we emphasize and strongly encourage our customers to concentrate on, "lips together, teeth apart" lips together, teeth apart" to initiate the muscle relaxation learning process. When directed by the brain, muscles at ease will allow the teeth to rest on the bitepads. Do not push down, although the natural urge to do so will test your mental approach to learning "lips together, teeth apart".

How do I fit the SleepRight Night Guard?

Detailed pictures are included with easy to follow care and fitting instructions. With SleepRight's patented adjustable technology, you have four bitepad positions, making it possible to customize the size to fit most people. The thermal sensitive strap, which is positioned between your lower lip and teeth, will adapt to your gums when heated under warm water. Do not boil the SleepRight Night Guard.

How does the SleepRight Night Guard stay in place?

The SleepRight Night Guard utilizes natural tissue retention between your lips, cheek, and tongue to be held in place. There are no clasps that attach to the teeth and you do not need teeth to hold the appliance in place. While the bitepads are made of a tough and resilient material, the heat sensitive memory strap is smooth, soft, and flexible. This enhances adaptation to each individual's anatomy.

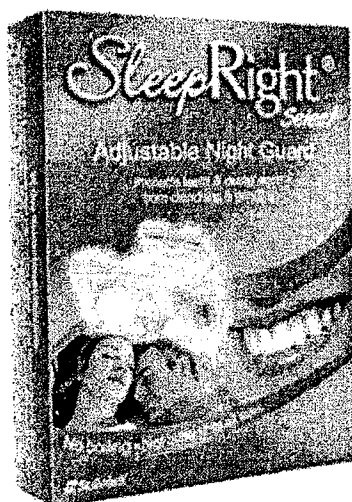
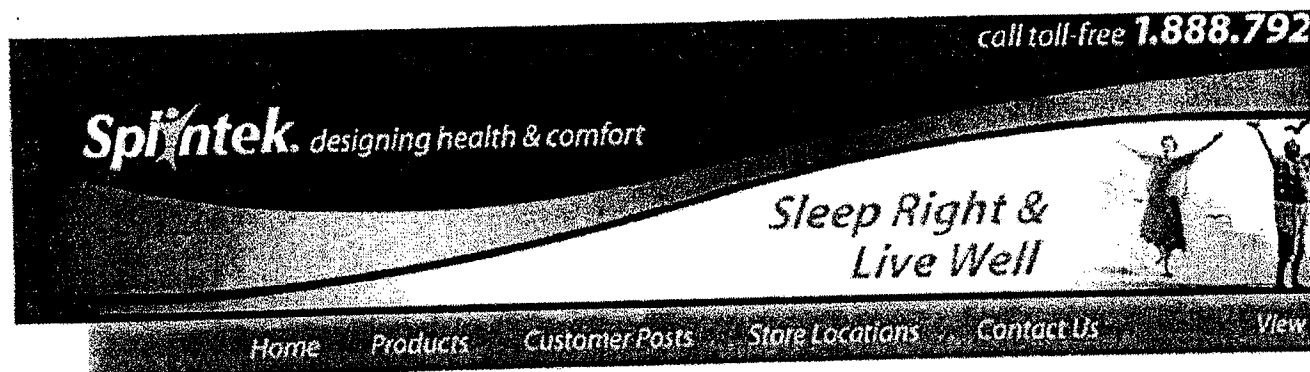
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SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

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SleepRight[®] Select

SleepRight Advance
SleepRight Select Low-Profile

Frequently Asked Questions
Philosophy
Care & Fitting Instructions
Satisfied Customers



SleepRight Select is the original design that fits n individuals and recommended for sleep.

Select Flavor

Buy Now

\$69.95 each (\$59.95 each for 2 or more)

Available in natural mint flavor or cinnamon flavor.

Includes one night guard, one carrying case, and fitting instructions.

30-Day Money Back Guarantee
If you are dissatisfied with the SleepRight Night Guard for any reason, simply return it to the place of purchase within 30-days from original purchase date for a refund.

90-Day Replacement Warranty
SleepRight is the most durable night guard on the market. If you clench or grind though the SleepRight Night Guard within 90-days from original purchase date, simply send the used night guard to

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SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

Page 2 of 2

Splintek, 3325 Wyoming St., Kansas City, MO 64111. You must include proof of purchase, your name, and return address. Please allow up to 2 weeks to receive your replacement.

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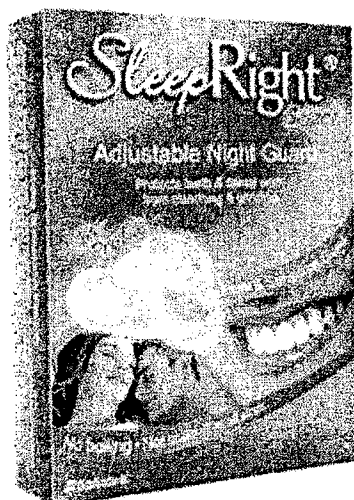
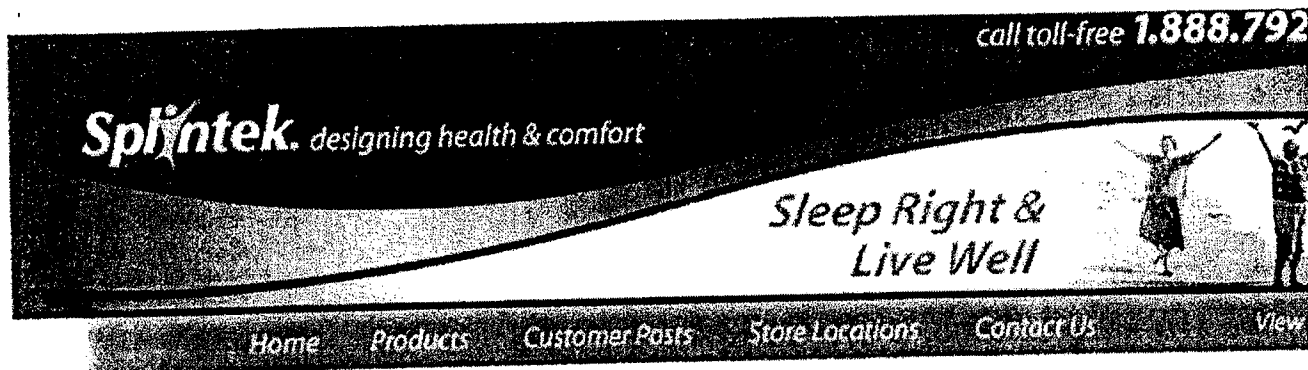
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SleepRight Night Guard Protects Teeth From Teeth Grinding and Clenching

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Low-Profile

SleepRight[®]
SelectSleepRight Advance
SleepRight SelectFrequently Asked Questions
Philosophy
Care & Fitting Instructions
Satisfied Customers

 SleepRight Select Low-Profile is recommended for sensitive gums and/or a small mouth.

Select Flavor

Buy Now

\$69.95 each (59.95 each for 2 or more)

Available in natural mint flavor or cinnamon flavor.

Includes one night guard, one carrying case, and fitting instructions.

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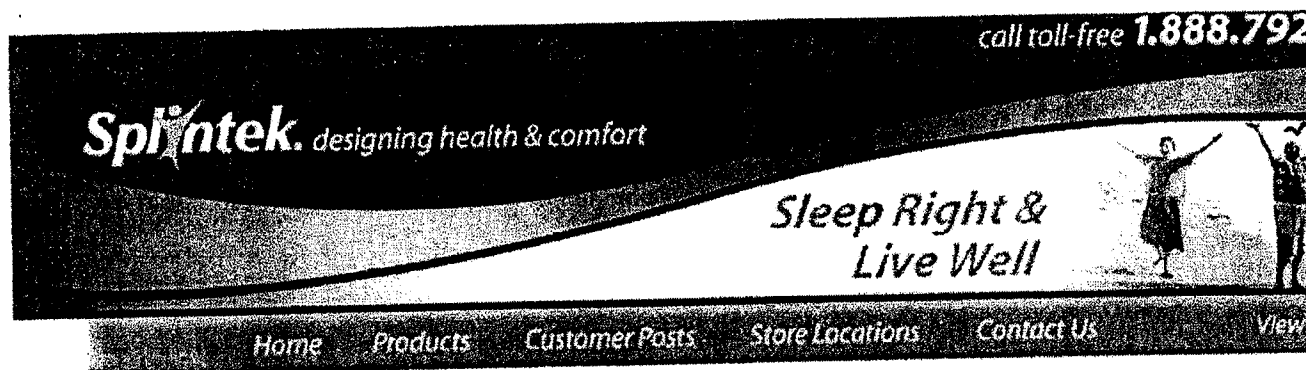
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SleepRight™ Side Sleeping Pillow

Helpful Hints
Satisfied Customers
Pillow Sizing Tool

Sleep studies indicate that side sleeping habits are 95% more prevalent when compared to sleeping on the back. Orthopedically correct side sleeping posture is now made possible by the latest in sleep technology with the SleepRight Side Sleeping Pillow. With the SleepRight state-of-the-art design, you can expect restful sleep with maximum support and superior comfort for the head, neck, and shoulders.

What is the SleepRight Pillow made of?

The SleepRight Side Sleeping Pillow is made from premium Visco-elastic memory foam, originally developed by NASA. This pressure relieving memory foam is sensitive to body temperature and weight, easily conforming to your own personal anatomy. We guarantee our pillows to be made of the highest quality memory foam available with a 5-year warranty. Includes a machine washable, hypo-allergenic, cotton velour cover. However, if desired, your favorite standard pillowcase provides a nice feel without the velour cover.

How does the SleepRight Pillow work?

The Visco-elastic memory foam conforms to your facial contours by taking an impression of your head and neck anatomy. This greatly minimizes the unwanted side effects of pressure points, which is a benefit unavailable in regular pillows. As your head settles into the full facial cradle, the memory foam will softly conform to your personal anatomy. The memory foam will automatically adjust to your body temperature and head weight as your head and neck stabilize in its resting place. When equalization between head weight and the elasticity of the memory foam is achieved, your head and neck posture will be ideally aligned with your spinal column.

The Design

The SleepRight Side Sleeping Pillow has three important design features, which distinguish it from all other memory foam pillows.

The full facial cradle gently cradles the face while reduces pressure points on the jaw and ear. This means increased blood flow to the facial dermal cells while sleeping, reducing the tendency for facial tissues to crease or sag.

The 12° shoulder cradle accommodates the acute angle between



Select Size

[Buy Now](#)

16" x 12" x 3" - \$69.95
16" x 12" x 4" - \$69.95
24" x 12" x 3" - \$99.95
24" x 12" x 4" - \$99.95
24" x 12" x 5" - \$109.95

16" Length - Ideal for travel
24" Length - Standard pillow that fits most pillow

3" Petite Adult - For 5'4" and shorter
4" Standard Adult - For 5'5" and taller
5" Large Adult - For 5'10" and taller (broad shoulder frames)

Includes one memory foam pillow and one machine washable, hypoallergenic, cotton velour cover.

SleepRight System! Purchase a 16" pillow for 24" pillow for \$50 when you purchase it with a SleepRight Adjustable Night Guard! Must place

SleepRight Memory Foam Pillow Provides Orthopedic Support For Side Sleepers

Page 2 of 2

your head, neck, and shoulder while sleeping on your side. You will experience significant improvement in your spinal alignment between the neck and back. The anatomical shoulder cradle will reduce the body weight impact on the shoulders, increasing blood flow to the arms.

The left and right airway system maximizes airflow to help you experience improved breathing. Some users have reported a reduction in snoring.

order over the phone to receive this discount.
1.888.792.0865

All sales are final on bedding products.

5-Year Warranty

You may exchange the SleepRight Side Sleepir for a replacement within 5 years from the original purchase date. Simply send the used pillow to S 3325 Wyoming St., Kansas City, MO 64111. You include proof of purchase, your name, and return address. Please allow up to 2 weeks to receive replacement.

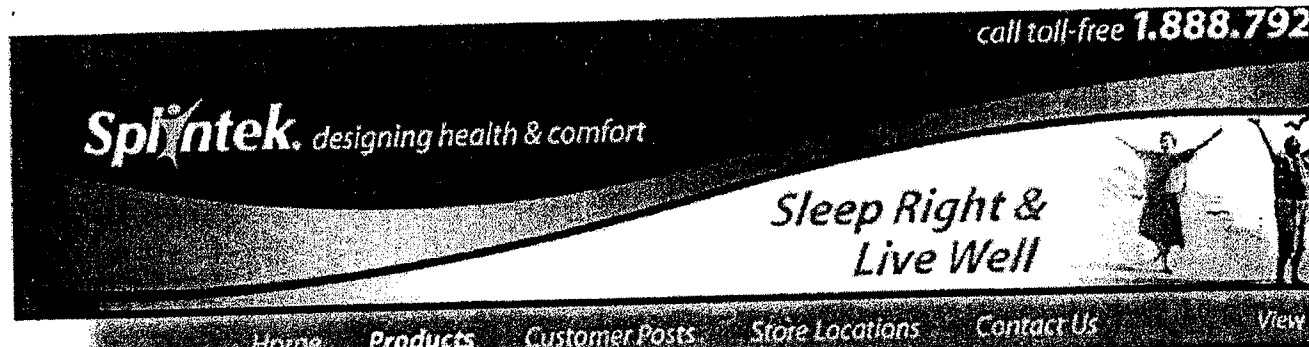
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ERGOPIC

The ErgoPic is designed with an easy to hold ergonomic finger tab and two different tips. One tip features a patented cleaning texture for interproximal cleaning between teeth. The other is designed to clean plaque around gum lines while stimulating healthy gingival tissues. Each pic is made of durable polypropylene for extended use without splintering or breaking.

Please call to order: 1.888.792.0865

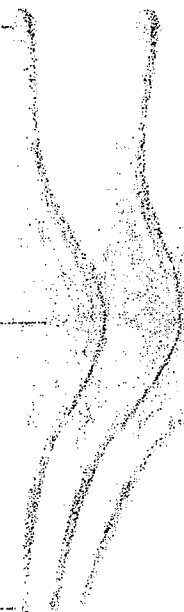
\$6.95

Includes 50 dental pics and one carrying case.

Stimulates and cleans
gum line

Ergonomic finger tab

Textured for cleaning
between teeth



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| Support | | | |
| Questions A forum for customers with questions for Splintek. Moderator Jessica | 48 | 112 | Wed Sep 27, 2006 7:41 am RachelM → |

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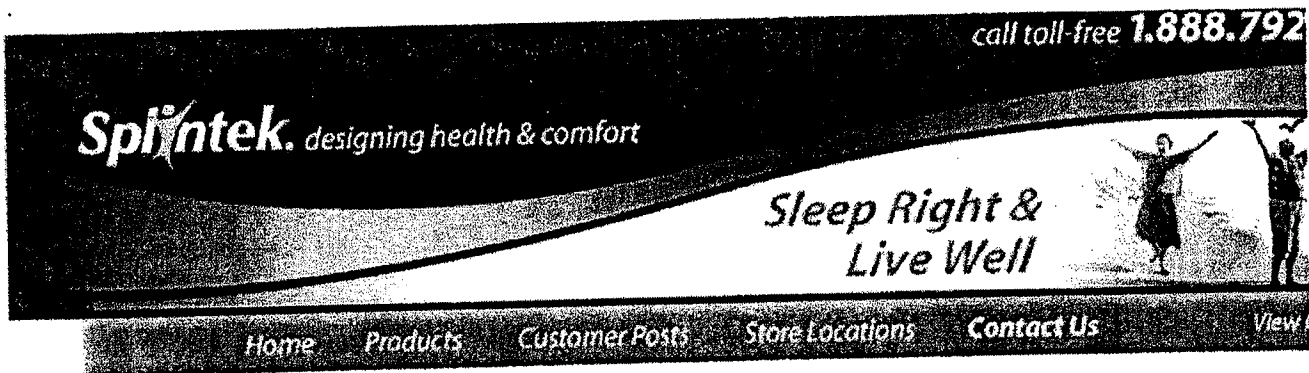
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Contact Us

Feel free to contact our knowledgeable service representatives by phone, fax, or email.

Toll-Free 1.888.792.0865
Local (816) 531-1900
Fax (816) 531-1968

General Information: sales@splintek.com
Customer Support: support@splintek.com

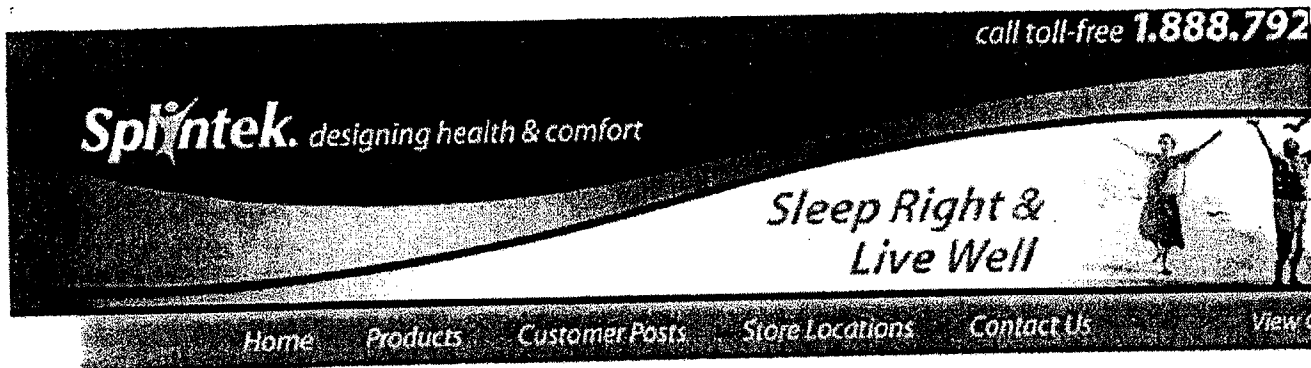
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Night Guard Protects From Teeth Grinding And Clenching

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Refer-A-Friend You can receive 10% discount on your next order by referring a friend to us. Just call us and tell us the name of your friend you referred. Use promotional code: **RAFF10** (cannot be combined with any other discount)

SleepRight System! Receive a large discount on the SleepRight Side Sleeping Pillow when purchased with a SleepRight Adjustable Night Guard. Must call to receive discount.

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